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13. ABSTRACT *(Maximum 200 words)*

This research investigates an important application of full-field direct digital mammography (FFDDM): telemammography, the electronic transfer of digital mammography images to remote viewing sites. This should permit radiologists with great interpretive expertise to manage and read in real time *all* mammography examinations in a multiple-site practice, an approach superior to either deferred interpretation by expert readers or real-time interpretation by general radiologists. During Year 2 of this project, we acquired a large data set of FFDDM cases and demonstrated that remote interpretation of these images by expert mammographers is as effective (slightly better, but difference not statistically significant) as conventional film interpretation by general diagnostic radiologists. By showing that telemammography technology can be developed for routine clinical operation, and that real-time off-site management and interpretation of a general-radiologist mammography practice by mammography specialists is feasible as standard operating procedure, we expect to establish telemammography applications of digital radiography as both valid and useful. The application of these procedures to routine mammographic examinations should bring to bear the expertise of mammography specialists at the community-practice general-radiologist level. This should benefit all women undergoing mammography in the future.

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FOREWORD

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Edward A Sickles MD 10/6/98

PI - Signature Date

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INTRODUCTION

Current attempts at controlling breast cancer concentrate on early detection by means of mass screening, using periodic mammography and physical examination, because ample evidence is now available to indicate that such screening indeed can be effective in lowering the death rate.

Screen-film mammography has several technical limitations which reduce its effectiveness, most of which can be overcome by full-field direct digital mammography (FFDDM) [1,2]. The principal theoretical advantage of FFDDM comes from decoupling image display from the image receptor. This permits the digital image to be captured electronically, stored digitally, and then manipulated, analyzed, and displayed however, whenever, and wherever it is needed. Practical applications of FFDDM currently under development include: real-time image display, post-acquisition image enhancement, image archival and retrieval, dual-energy subtraction imaging, computer-aided diagnosis, and computer-aided instruction.

This research will investigate still another application of digital breast imaging: teleradiology mammography, or telemammography [1,2]. Electronic transfer of digital images to remote viewing sites can be accomplished almost as rapidly as between the standard display workstation and computer storage. Radiologists who work in several different offices or hospitals will be able to monitor and interpret examinations that are carried out in a nearby or even at distant location or locations. This will permit those radiologists with the greatest interpretive expertise to manage and read in real time *all* mammography examinations, an operational procedure far superior to the alternative of choosing between deferred interpretation by expert readers or real-time interpretation by general radiologists [3,4]. In addition, mammography screening in mobile units will be made more efficient, not only by overcoming the need to transport films from the site of examination to the site of interpretation, but also by permitting image interpretation while patients are still available for repeat or additional exposures. Telemammography can also be used to facilitate second-opinion interpretation, in effect making world-class mammography expertise immediately accessible to community-practice radiologists. Finally, digital image transmission can be the cornerstone upon which multi-site teaching conferences are built, from applications as simple as the simultaneous conduct of teaching rounds among the nearby hospitals that participate in a residency training program to intercontinental multi-institution conferences supported by satellite transmission of digital mammograms.

The majority of the clinical activities of the breast imaging service at our institution take place in the Breast Imaging Section of UCSF/Mt. Zion Medical Center, staffed by full-time breast imaging specialists. Additional mammography examinations are done at the UCSF/Parnassus Ambulatory Care Center (ACC), staffed by general diagnostic radiologists. During the conduct of this study, the UCSF/Mt. Zion Medical Center will serve as the site of great interpretive expertise, whereas the UCSF/Parnassus ACC will be a satellite site staffed by general radiologists.

By demonstrating that [a] telemammography technologies can be developed for routine clinical operation, and [b] that real-time off-site management and interpretation of a general-radiologist mammography practice by mammography specialists is feasible as standard operating procedure, we will help to establish telemammography applications of

digital radiography as both valid and useful. The application of these procedures to routine mammographic examinations should contribute to more efficient and higher quality breast imaging, by bringing to bear the expertise of mammography specialists at the community-practice general-radiologist level. This should benefit all women undergoing mammography in the future.

BODY

Seven tasks were outlined in the Statement of Work within our grant proposal. All of the Year 1 tasks were accomplished as initially planned. These involved the development of telemammography infrastructure: (*a*) creation of a telemammography network, (*b*) installation of the first (of two) FFDDM units at UCSF/Mt. Zion Medical Center, (*c*) development of a digital mammography display workstation (DMDW), and (*d*) integration of the above-described systems.

When we initially developed our digital mammography display workstation (DMDW), we planned on using images having a matrix of 4,095 x 5,120 (40-Mbyte per image). However, Fischer Imaging Corp. supplied us with an improved-image-quality second-generation FFDDM unit, which utilized an image area (4,095 x 5,625; 46-Mbyte per image) somewhat larger than that of their first-generation FFDDM unit. This increase in image file size affected our DMDW system memory capacity such that we were unable to simultaneously display eight digital images on the DMDW. However, during Year 2, we increased the amount of system memory installed in the DMDW from 384 Mbytes to 512 Mbytes, so that now we have no difficulty displaying simultaneously eight digital images on the DMDW.

During Year 1 and the first half of Year 2, we not infrequently experienced the problem of drop-out of image pixels when digital mammogram data were transmitted from the FFDDM imager to the capture computer. When this problem occurred, the capture computer system hung up, resulting in lack of completion of the mammogram to be stored onto disk, and inability to use the FFDDM images for subsequent analysis. We solved this problem by the end of the first half of Year 2, in part by upgrading our ATM software device driver. As a result, during the second half of Year 2, we have been able to acquire acceptable FFDDM images on virtually all patients recruited for the project. Indeed, we have acquired 362 useful FFDDM cases in the second half of Year 2, compared to only 79 cases acquired previously.

As initially planned for completion in Year 2, we acquired 400 FFDDM cases (actually we acquired 441 cases) employing the unit already installed at UCSF/Mount Zion Medical Center, for use in our telediagnosis protocol. The other major activity scheduled for Year 2 involved installation of a second FFDDM unit at the UCSF/Parnassus ACC and completion of the final telemammography chain to incorporate this second FFDDM unit into the existing network. However, because the manufacturer of our FFDDM equipment was unable to deliver the second unit during Year 2 (see letter from Fischer Imaging Corp. in the Appendix), we were unable to proceed apart from planning for space renovation at the ACC.

Since we needed to free up extra time in Year 3 to install our second FFDDM unit at the UCSF/Parnassus ACC and to establish the telemammography chain in its final form, we chose to perform the telediagnosis protocol in Year 2, instead of performing it in Year 3 as initially planned. This was made possible because we had already acquired all the FFDDM cases required for the telediagnosis protocol before the end of the second half of Year 2. Note that this change in sequence of work in no way compromises the experimental design of the overall project, because the case material for telediagnosis was to be derived from FFDDM examinations performed at UCSF/Mount Zion Medical Center, and because the telediagnosis protocol had to be completed successfully before proceeding to the teleconsultation and telemanagement protocols.

As stated previously, we acquired more than 400 FFDDM cases from the UCSF/Mount Zion Medical Center. From these cases, we selected appropriate numbers of normal and abnormal cases for image interpretation study, according to the plan described in our grant proposal. Indeed, the entire telediagnosis procedure was carried out exactly as described in the grant proposal. The aim of the telediagnosis protocol was to evaluate the accuracy of interpretation of transmitted FFDDM images by expert mammographers as compared to the interpretation of conventional film mammograms by general diagnostic radiologists. We imposed identical controls on viewing conditions for both conventional film mammograms and FFDDM images to eliminate environmental discrepancies in image interpretation. We also utilized our established image quality criteria for both conventional film and FFDDM images to eliminate the possibility that image quality discrepancies might bias interpretation. Results of the image interpretation study indicated that both sensitivity and specificity were somewhat higher (improved) for FFDDM interpretation than for conventional film interpretation. These differences were not statistically significant. We therefore can conclude that interpretation of transmitted FFDDM images by expert mammographers is no less accurate than that of conventional film mammograms by general diagnostic radiologists. This basic observation permits us to proceed with our planned teleconsultation and telemanagement protocols, both of which are designed to establish the utility of telemammography applications in routine clinical practice.

During Year 3 of the project, after installation and networking of our second FFDDM unit at the UCSF/Parnassus ACC (to be completed by month 27, as discussed subsequently), we plan to conduct the remaining two telemammography study protocols: teleconsultation, and telemanagement (months 28-36). The teleconsultation protocol tests the clinical effectiveness of digital mammography consultation between general radiologists and expert breast-imaging radiologists, using selected difficult mammography cases. The aim here is to evaluate the ability of telemammography to facilitate real-time consultation between on-site general diagnostic radiologists and remotely-located expert breast-imaging radiologists. The telemanagement protocol tests the effectiveness of remote real-time interpretation and management of digital mammography examinations by expert breast-imaging radiologists (versus real-time on-site interpretation and management of conventional screen-film mammograms by general

diagnostic radiologists). If telemanagement succeeds, this will permit the replacement of on-site general radiologists with remotely-located expert breast-imaging radiologists.

We now discuss the current status of each of the seven tasks within the Statement of Work in our grant proposal.

Task 1. Set up the first FFDDM system at UCSF/Mount Zion Medical Center. By the end of Year 1, we had completed all six components of this task, as reported in last year's annual report, which was judged "acceptable as written".

Task 2. Telemammography chain – part 1. By the end of Year 1, we had completed all five components of this task, as reported in last year's annual report, which was judged "acceptable as written".

Task 3. Installation of the second FFDDM system at the UCSF/Parnassus ACC. During Year 2, we completed planning for space renovation at the ACC [part of sub-task (a)]. However, since the manufacturer of our FFDDM equipment has not yet delivered the second unit, we have been unable to complete the rest of Task 3. Since the component sub-tasks are identical to those already completed in Task 1, and since we have already solved most (probably all) logistic problems in installing our first FFDDM unit, we expect no problem in completing Task 3 by the end of the first quarter of Year 3. This is because we expect delivery of the second FFDDM unit during the first week in November 1998 (see Appendix).

Task 4. Telemammography chain – part 2. Since the manufacturer of our FFDDM equipment has not yet delivered the second unit, we have been unable to complete Task 4, which can be done only after this second unit is successfully installed at the UCSF/Parnassus ACC. Since the component sub-tasks are identical to those already completed in Task 2, and since all logistic problems involved in assembling our telemammography chain have already been worked out during Year 1, we expect no problem in completing Task 4 by the end of the first quarter of Year 3.

Task 5. Telediagnosis. All components of the telediagnosis protocol have been completed in Year 2, rather than in Year 3 as initially planned. We have acquired more than the required number of normal and abnormal FFDDM cases, selected 400 cases for study, and set up the telediagnosis procedure exactly as indicated in our grant proposal. We also corrected for possible environmental and image quality discrepancies in carrying out the protocol. We then performed the planned image interpretation study, comparing the performance of general diagnostic radiologists using conventional film images versus expert mammographers using transmitted FFDDM images. Completion of the telediagnosis protocol in Year 2 frees up the needed time in Year 3 for us add the implementation of Tasks 3 and 4 to our Year 3 work.

Task 6. Teleconsultation. As indicated in our initial grant proposal, this activity has been planned for Year 3. We must first complete installation of the second FFDDM unit at the UCSF/Parnassus ACC and then assemble the final telemammography chain (Tasks

3 and 4, to be done during the first quarter of Year 3). Based on our demonstrated ability to acquire FFDDM cases at a much faster than expected rate during the second half of Year 2, we expect to be able to complete this protocol during only three quarters of (rather than all of) Year 3.

Task 7. Telemanagement. As indicated in our initial grant proposal, this activity has been planned for Year 3. We must first complete installation of the second FFDDM unit at the UCSF/Parnassus ACC and then assemble the final telemammography chain (Tasks 3 and 4, to be done during the first quarter of Year 3). Based on our demonstrated ability to acquire FFDDM cases at a much faster than expected rate during the second half of Year 2, we expect to be able to complete this protocol during only three quarters of (rather than all of) Year 3.

There already have been three scientific publications of the work produced by our project. These are listed below, with full reference citations.

Year 1. Lou SL, Sickles E, Huang HK, Cao F, Hoogstrate D, Jahangiri M. Full-field direct digital telemammography - preliminary. SPIE Proc Med Imaging 1997; 3035:369-379.

Year 1. Huang HK, Lou SL, Sickles EA, Hoogstrate D, Jahangiri M, Cao F, Wang J. Technical issues in full-field direct digital telemammography. *In* Lemke HU, Vannier MW, Inamura K, eds. Computer assisted radiology and surgery. Amsterdam, Elsevier Science, 1997:662-667.

Year 2. Lou SL, Sickles EA, Huang HK, Hoogstrate D, Cao F, Wang J, Jahangiri M. Full-field direct digital telemammography: technical components, study protocols, and preliminary results. IEEE Transact Inform Tech Biomed 1997; 1:270-278.

CONCLUSIONS

Work on this project is proceeding, reasonably on schedule, despite several unanticipated delays. By the end of Year 1 of the project, we installed the first of two full-field direct digital mammography (FFDDM) imagers, developed a digital mammography display workstation, and developed the infrastructure and begun the clinical use of a telemammography chain between the Breast Imaging Section at UCSF/Mt. Zion Medical Center and the Laboratory for Radiological Informatics at UCSF/Parnassus Medical Center, two miles apart. By the end of Year 2 of the project, we acquired a large data set of FFDDM cases and demonstrated that remote interpretation of these images by expert mammographers is as effective (slightly more effective, but difference not statistically significant) as conventional film interpretation by general diagnostic radiologists. By the end of the project, we expect to demonstrate that [a] telemammography technology can be developed for routine clinical operation, and [b] that real-time off-site management and interpretation of a general-radiologist mammography practice by mammography specialists is feasible as standard operating procedure, thus helping to establish

telemammography applications of digital radiography as both valid and useful. The application of these procedures to routine mammographic examinations should contribute to more efficient and higher quality breast imaging, by bringing to bear the expertise of mammography specialists at the community-practice general-radiologist level. This should benefit all women undergoing mammography in the future.

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[2] Huang HK. Elements of digital radiology; a professional handbook and guide. New Jersey, Prentice-Hall, 1987.

[3] Sickles EA, Ominsky SH, Sollitto RA, Galvin HB, Monticciolo DL. Medical audit of a rapid throughput mammography screening practice: methodology and results of 27,114 examinations. Radiology 1990; 175:323-327.

[4] Sickles EA. Quality assurance: how to audit your own mammography practice. Radiol Clin North Am 1992; 30:265-275.

APPENDIX

The following page contains an explanatory letter from Fischer Imaging Corp., describing their inability to deliver the second FFDDM unit to us during Year 2 of our project. However, production of the second unit is now well underway, and as indicated in the letter, we expect delivery at the UCSF/Parnassus ACC during the first week in November 1998.

FISCHERIMAGING
CORPORATION

October 1, 1998

Dr. Edward Sickles, M.D.
2330 Post St. Room 180
San Francisco, CA 94115

Dear Dr. Sickles,

The purpose of this memo is to give you the status of the second Senoscan® digital mammo unit. As I mentioned to you verbally, we have made a number of design changes on this unit which will improve the serviceability, performance and ease of installation, especially with respect to isolating the system from it's room environment.
Because of these changes we have experienced some delay in delivering this system. At this time we are confident that the installation will begin during the first week of November.
I apologize for whatever inconvenience this might have caused you.

Sincerely yours,

Mike M. Tesic, Ph.D
V.P. Engineering

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